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DOCUMENT DESCRIPTION	DOCUMENT CONTROL NUMBER	DATE RECEIVED
8EHQ-09-17484	89110000173	3/15/11

COMMENTS: COMMUN S (DECLASS)

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Givaudan®

March 11, 2011

Via email and USPS

Matthew G. Leopard, Director  
Information Management Division  
USEPA Headquarters  
Ariel Rios Building  
1200 Pennsylvania Avenue, N. W.  
**Mail Code:** 7407M  
Washington, DC 20460



Re: Withdrawal of Confidentiality Claims

Dear Mr. Leopard,

We are writing in response to three letters from you dated February 8, 2011 regarding claims of confidentiality for the identity of five chemical substances that were the subject of reports under Section 8(e) of the Toxic Substances Control Act ("TSCA") dated March 27, 2006, July 1, 2008, and April 21 and May 19, 2009. Givaudan hereby withdraws all claims of confidentiality made with respect to the Section 8(e) reports in question. This withdrawal relates only to the five reports referenced in your letters, not to any other submission that Givaudan may have made under TSCA.

Please note this withdrawal of confidentiality is intended only to allow EPA to reveal to the public the information that was claimed confidential at the time of the reports in question. Givaudan is not relinquishing any property rights in the studies in question.

If you have any questions regarding this letter, please contact our counsel, Thomas B. Johnston, McKenna Long & Aldridge LLP, at (202) 496-7656.

Sincerely,

Greg Adamson, Ph.D.  
Vice President Regulatory Affairs & Product Safety  
Givaudan Fragrances Corporation

cc: Mr. Scott M. Sherlock (OPPTS)  
Mr. Ryan Wallace (OPPTS)



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Writer's Direct Access  
Justin C. Powell  
(202) 434-4121  
powell@khlaw.com

April 21, 2009

Via Courier



~~CONTAINS TSCA CONFIDENTIAL~~  
~~BUSINESS INFORMATION~~ RAW

TSCA Confidential Business Information Center (7407M)  
EPA East - Room 6428 Attn: Section 8(e)  
U.S. Environmental Protection Agency  
1201 Constitution Avenue, N.W.  
Washington, DC 2004-3302



**Re: Givaudan Fragrances Corporation; Submission of Preliminary Test Results  
Under Section 8(e) of TSCA for 4-(1,1-Dimethylethyl)benzenepropanal,  
CASRN 18127-01-0**

Dear Sir or Madam:

On behalf of our client, Givaudan Fragrances Corporation (Givaudan), we are advising the U.S. Environmental Protection Agency (EPA) of preliminary findings from a feeding study in rats with 4-(1,1-dimethylethyl)benzenepropanal, which has Chemical Abstracts Service Registry Number (CASRN) 18127-01-0. This notice is in accord with section 8(e) of the Toxic Substances Control Act (TSCA) as interpreted in *TSCA Section 8(e) Notification of Substantial Risk; Policy Clarification and Reporting Guidance* (68 Fed. Reg. 33,129, Jun. 3, 2003) and *TSCA Section 8(e) Reporting Guidance; Correction, Clarification of Applicability, and Announcement Regarding the Issuance Questions and Answers* (70 Fed. Reg. 2162, Jan. 12, 2005). Providing this information in a timely manner to the Agency is consistent with Givaudan's commitment to product stewardship.

The preliminary, unaudited results from a five-day, oral gavage study in mature male Crl:CD(SD) rats were received by Givaudan on March 24, 2009. Three groups of six animals per group were dosed with 25, 100, or 250 mg/kg/day respectively of the test substance. The negative control consisted of only the vehicle, corn oil; the positive control was 250 mg/kg/day of 4-(1,1-dimethylethyl)- $\alpha$ -methylbenzenepropanal, CASRN 80-54-6. Givaudan previously submitted section 8(e) notices reporting testicular effects for the positive control in 1990 and 1991.

The purpose of the subject study was to examine the effects of the test substance on the reproductive organs of male rats. At the start of dosing, the rats were 11 weeks old and weighed between 328 and 373 g. Gross pathology, clinical chemistry, and histopathology of all terminally sacrificed animals were completed. Below, we provide a summary of the preliminary findings from unaudited data of macropathology and histopathology following the completion of the in-life phase.

Washington, D.C.

Brussels

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April 21, 2009

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There were no macroscopic observations noted in the group dosed at 25 mg/kg/day of the test substance.

At the dose of 100 mg/kg/day of the test substance, one animal in moribund condition was sacrificed on day one. The five remaining animals survived the treatment period. These five animals exhibited treatment-related effects in the testes and epididymides. All five animals exhibited marked atrophy of the seminiferous tubules, marked vacuolization of the Sertoli cells, minimal multinucleated giant cells, and moderate to marked luminal sloughing of spermatogenic cells. In the epididymus, there was minimal reduced sperm count in one animal, slight sperm count reduction in two animals, and moderate sperm count reduction in two animals. There was also moderate inflammation of the epididymus in two of the five animals.

At the dose of 250 mg/kg/day of the test substance, three moribund animals were sacrificed on day one for welfare reasons following severe clinical signs (prostration, piloerection, partially closed eyelids, reduced body temperature, no righting reflexes). The remaining three animals from the high dose group were sacrificed on the morning of day two, prior to dosing due to the insufficient size of the remaining group.

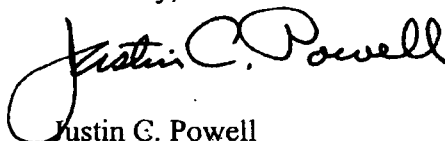
Effects observed in the control groups were as expected. Animals in the positive control group showed effects that were similar to those observed in animals treated with the test substance. One animal in the positive control group was found dead on day six. No adverse observations were made on the reproductive organs of the animals in the negative control group.

Enclosed, please find a copy of this letter with confidential information redacted. In addition we enclose a CBI copy of the answered CBI substantiation questions according to the instructions located in the TSCA section 8(e) website:

<http://www.epa.gov/oppt/tscase/pubs/confidentialbusinessinformation.htm>.

The completed study report has not been issued. Givaudan plans to forward a copy of the completed study report to the EPA after it is received. In the meantime, if there are any questions, please do not hesitate to contact me at 202.434.4121.

Sincerely,



Justin C. Powell  
Outside Counsel for  
Givaudan Fragrances Corporation

Enclosures

cc: J. Zangaro, Esq.  
G. Adamson, Ph.D.